

REMARKS**Objections to Drawings under 37 CFR § 1.84(p)(5)**

Applicants herewith submit a new copy of corrected Figure 9, originally submitted with the Preliminary Amendment of February 14, 2001, but apparently missing from the file. Along with the new copy of corrected Figure 9 is a copy of the letter to the master draftsman, also submitted with the Preliminary Amendment of February 14, 2001, and a copy of the return postcard showing that both the corrected drawing and the letter to the master draftsman was received by the USPTO on February 23, 2001.

The correction to Figure 9 corresponds to the correction in the specification, changing locking mechanism **916** on p. 13, lines 4-5 and in Figure 9 to locking element **940**, because element **916** was already used and assigned to the endoscope passageway on p. 12, line 5 and in Figure 9. Applicants respectfully submit that the drawings now meet the requirements of 37 CFR §1.184(p)(5), and that no new matter is added with this correction.

Claim Rejections under 36 U.S.C. § 112, para. 2.

Claim 1 is herein amended to address the issue of no antecedent basis for “at least one gas supply port on the head” which term is amended to state “at least one fluid supply port on the head.” Support for the amendment is found in the application on p. 6, lines 21- 23 (“shaft **12** is sized to provide flow paths *both* for the gas ... *and for saline solution* to the head”) and lines 27-29 (“The head **11** is provided with an opening that holds .. and also provides exit orifices for *the gas and saline solution*”), emphasis added. Further support is found on p. 7, lines 9-11 (“The tip of head **11** contains ... a plurality of ports **24** for the delivery of *gas and/or saline solution*”), emphasis added, and in Figure 2a, elements **24**.

Claims 7-8 and 14 are herein amended to correct the misspelling of the word “endarterectomy”. Applicants respectfully submit that no new matter is added with any of these amendments.

Claim Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-6 for as being unpatentable over Newman et al. (U.S. Patent No. 5,954,713), stating that although “Newman et al. do not explicitly recite a flow valve it would be obvious ... to modify the invention of Newman et al. to include a flow valve, ...for it is **necessary** to control the flow...” See p. 3 of the Office Action. Applicants respectfully submit that none of the prior art, including Newman et al, as conceded by the Examiner, shows a flow valve in an endarterectomy surgical instrument. Further, merely because the Examiner contends it is necessary to control the flow does not mean that it is obvious to: a) have the control be a valve; b) have the control be a flow valve for metering in the endarterectomy instrument itself that can be operated directly by the surgeon during surgery. An instrument with a control valve in the handle provides significant advantages over conventional on/off metering done remote from the surgical site by someone other than the surgeon in the act of performing surgery. Nothing in Newman et al. suggests the specific means for controlling flow required by the presently claimed invention – “a flow valve for metering flow of gas between the gas supply line and the at least one fluid supply port in the head” – in the actual endarterectomy instrument itself, and nothing in the knowledge generally available suggests that control of flow should be placed in the handle of the endarterectomy device itself.

Claims 7-11 and claims 13-14 are rejected as being unpatentable over Newman et al in view of Matsui et al. (U.S. Patent No. 6,352,503). The Examiner states that

although “Newman et al. do not recited the grasping device … Matsui at al. [discloses] a grasping device…” and that it would be obvious to modify Newman et al. to include a grasping device. See Office action, p. 5. Matsui et al. discloses an endoscopic surgery apparatus for performing treating operation in a body cavity … with the use of cutting tools in combination with an endoscope in which … a balloon is provided…” See Matsui et al., Abstract. Matsui et al. discloses grasping devices or cutting tools at the ends of insertion sections (see Figs. 1 and 11, for example) that are used to hold tissue, cut tissue, sew sutures, and/or cut sutures for performing treating operation in a body cavity of a patient (see claim1, and col. 9. lines 39-63; col. 10, lines 44-67) wherein the treating operations performed in the body cavity are “applied to the upper digestive system, such as the esophagus, stomach, duodenum, etc.” and to “the lower digestive system, that is, the large intestine” (see col. 11, lines 13-27). In short, Matsui et al. is not designed for use in the small, narrow passageway between the interstitial and media layers of an artery, and would not work in such a situation, because Matsui et al. requires a balloon, or “basket-like structure capable of being expanded or contracted” or in the language of the claims, “a distance adjusting device for adjusting a relative distance between at least one pair of the observation device of the endoscope, insertion section of the first treating tool and insertion section of the second treating tool” (see col. 7, lines 28-34 and claim 1) and the grasping device of Matsui et al., such as it is, is connected to the insertion sections of the surgical device. Combining the grasping device of Matsui et al. with the endarterectomy of Newman et al. is not suggested in either reference and one of ordinary skill in the art would not find the motivation to combine them in the knowledge generally available in the field because the Newman and Matsui devices are for totally different types of surgery, on totally different types, and sizes, of body tissue.

The Examiner has also rejected claims 7 and 12-13 under 35 U.S.C. § 103(a) as being unpatentable over Newman et al. in view of Deaton et al., stating that Deaton teaches “a grasping device (such as 100) having a retracted configuration and a deployed configuration....” Applicants respectfully submit that the Examiner has mis-interpreted Deaton et al. Element **100** in Deaton et al. is a flat, flexible cutting tool, it is not a grasping device and has no retracted configuration, let alone a deployed configuration (see Figs. 1, 2, and 3 especially, and col. 4, lines 52-64 etc.). It is possible the Examiner believes that element **124** of the broader element **100** is a grasping device, but in fact, careful reading of Deaton et al. clearly shows that element **124** is a guidewire (see col. 6, lines 26-31, and Figs. 5 and 6), that “helps to guide the flexible blade dissector **100** along the plane of separation S. The guidewire **124** and the flexible dissecting blade **102** are advanced, either sequentially or simultaneously, to widen and extend the plane of separation.” See col. 6, lines 30-36. Nowhere is element **124**, or the broader element 100, discussed, shown, or utilized as “a grasping device ... having a retracted configuration and a deployed configuration” as required by claim 1 as herein amended.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention unless there was some teaching, suggestion, or incentive in the prior art which would have made such a combination appropriate. See *e.g. Ashland Oil v. Delta Resins and Refractories, Inc.*, 766 F.2d 281 at 293 (Fed. Cir. 1985). One cannot argue obviousness based on the advantage of hindsight. The suggestion and motivation for a modification or combination must be present in the art itself, or the knowledge generally available in the field. The Examiner has provided no reference that teaches, or suggests modifying or combining references, which will lead to the claimed invention, whether having a flow valve built into the handle of the instrument itself, or

having a grasping device with a deployed position and non-deployed position suitable for use between the media and interstitial layers of the inside of an artery. As such, there is no *prima facie* case for obviousness.

CONCLUSION

For the reasons set forth above, it is submitted that all pending claims are in condition for allowance. Reconsideration of the claims and a notice of allowance are therefore requested. Applicants do not believe an extension of time is required. However, in the event that an extension of time has been overlooked, Applicants submit this conditional petition for an extension of time, and request that deposit account number 19-4972 be charged for any fees that may be required for the timely consideration of this application. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

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Respectfully submitted,



Barbara J. Carter
Registration No. 52,703
Attorney for Applicant
Bromberg & Sunstein LLP
125 Summer Street
Boston, Massachusetts 02110-1618
Tel: (617) 443-9292
Fax: (617) 443-0004

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